

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PERSONAL GENOMICS TAIWAN, INC.,)
)
Plaintiff,)
)
v.) C.A. No. _____
)
PACIFIC BIOSCIENCES OF CALIFORNIA, INC.,) JURY TRIAL DEMANDED
)
Defendant.)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Personal Genomics Taiwan, Inc. (“PGI”), by and through its undersigned counsel, pleads the following against Pacific Biosciences of California, Inc. (“PacBio”) and alleges as follows:

THE PARTIES

1. PGI is a corporation existing under the laws of Taiwan (R.O.C). The address of the registered office of PGI is 8 Shengyi Rd., Sec. 2, 4F, Hsinchu Biomedical Science Park, Zhubei, Hsinchu 30261, Taiwan (R.O.C.).

2. PGI is a research and development company focused on developing next generation sequencing technology, specifically in the field of single-molecule sequencing using semiconductor sensors instead of conventional optical tools.

3. PGI was founded in September 2010 as Crackerbio Taiwan, Inc., a spinoff from Industrial Technology Research Institute (“ITRI”). On November 18, 2010, ITRI granted Crackerbio Taiwan, Inc. an exclusive license to the technology in this case. Crackerbio Taiwan, Inc. later changed its English name to Ti-Shiue Biotech, Inc., and then to Personal Genomics

Taiwan, Inc. The Chinese name of this entity remained unchanged. Crackerbio Taiwan, Inc., Ti-Shiue Biotech, Inc. and Personal Genomics Taiwan, Inc. are referred to as “PGI.”

4. On June 10, 2019, ITRI assigned U.S. Patent No. 7,767,441 (“the ’441 Patent”) (Ex. 1) to PGI. PGI is the assignee and owns all right, title, and interest to the ’441 Patent.

5. On information and belief, Defendant PacBio is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1305 O’Brien Dr., Menlo Park, CA 94025.

6. PacBio manufactures, markets and sells “Sequel” and “Sequel II” sequencing devices that reportedly “deliver highly accurate long reads,” and provide “[h]igh-quality sequencing for genomes, transcriptomes, and epigenomes.” Ex. 2.

JURISDICTION AND VENUE

7. This is an action arising under the patent laws of the United States, 35 U.S.C. § 1 *et seq.* Accordingly, this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over PacBio because PacBio is incorporated in Delaware. On information and belief, PacBio also manufactures products that have been and are used, offered for sale, sold, and purchased in Delaware.

9. Under 28 U.S.C. § 1400(b), venue is proper in this judicial district at least because PacBio is incorporated in this district and therefore “resides” in this district.

BACKGROUND

10. PGI re-alleges and incorporates by reference Paragraphs 1-9 of its Complaint.

11. The technology described and claimed in the ’441 Patent originated from a project initiated by, among others, named inventor Dr. Chung-Fan Chiou at ITRI. This project focused on the novel use of a near-field complementary metal-oxide-semiconductor (“CMOS”) optical

sensor array in a single-molecule sequencer. ITRI filed patent applications on this innovative technology starting in October 2007, and initially referred to the technology as “s-TOP,” short for “Sequencing on Top of Photodiodes” or “Sequencing on Top of Pixel,” and later as “OES,” short for “OptoElectronic Sequencing.” The ’441 Patent claims priority to the October 2007 patent application.

12. On March 3, 2010, PacBio founder and Chief Technology Officer Dr. Stephen Turner contacted Dr. Chiou to express PacBio’s interest in the s-TOP sequencing technology. After PacBio and ITRI (PGI was not yet formed) signed a Non-Disclosure Agreement (“NDA”), Dr. Chiou provided to PacBio PowerPoint slides that included business and technical information regarding the s-TOP sequencing technology and referenced an October 2007 provisional patent application relating to the same. The ’441 Patent claims priority to this provisional patent application.

13. PGI and PacBio engaged in additional discussions in 2011. On July 28, 2011, several members from PGI met with PacBio at PacBio’s Menlo Park headquarters. After the parties signed another NDA, PGI presented to PacBio updates on PGI’s technology and the parties discussed a possible collaboration. The parties continued to discuss a possible collaboration over the next few months. This involved multiple in-person meetings, draft memoranda of understanding, a proposed term sheet to license PGI’s technology, which included the ’441 Patent, and a possible supply agreement. On December 1, 2011, Dr. Turner informed PGI that PacBio wanted to suspend negotiations.

14. Almost two years later, between September and November 2013, PacBio again contacted PGI regarding a potential non-exclusive worldwide license to PGI’s patented technology. Over the next several months, PGI continued to discuss a potential license and

business relationship with PacBio. In 2014, PacBio sent PGI a proposed term sheet to license the '441 Patent, among others. PGI and PacBio met for the last time on June 23, 2015. No further contacts between PacBio and PGI were made after this meeting.

15. On September 30, 2015, PacBio publicly announced the launch of a new product, the Sequel System ("Sequel"), stating in a press release that its new "nucleic acid sequencing platform" "provides higher throughput, more scalability, a reduced footprint and lower sequencing project costs compared to [its prior system]." Ex. 3. Sequel infringes the '441 Patent.

16. On April 24, 2019, PacBio publicly announced the launch of a new "SMRT Cell" (the "SMRT Cell 8M") and a new sequencer, the Sequel II System ("Sequel II"), which "is based on the proven technology and workflow underlying the previous version of the system, but contains updated hardware to process the new SMRT Cell 8M." Ex. 4. On information and belief, Sequel II uses the same sequencing technology present in Sequel, and differs primarily in the number of zero-mode waveguides ("ZMW") in the new SMRT Cell 8M required for sequencing on Sequel II. Accordingly, on information and belief, Sequel II infringes the '441 Patent for the same reasons as Sequel, discussed further below.

17. PacBio infringes the '441 Patent, literally or under the doctrine of equivalents, through its activities connected to its use, manufacture, sale, and importation of, for example, Sequel and Sequel II, as discussed below.

CLAIM FOR RELIEF

(Infringement of U.S. Patent No. 7,767,441)

18. PGI re-alleges and incorporates by reference Paragraphs 1-17 of its Complaint.

19. The '441 Patent, entitled "Bioassay system including optical detection apparatuses, and method for detecting biomolecules," was duly and lawfully issued August 3, 2010. A true and correct copy of the '441 Patent is attached hereto as Exhibit 1.

20. The '441 Patent names Chung-Fan Chiou, Cheng-Wei Chu, Shang-Chia Chang, Yu-Tang Li, Chao-Chi Pan, and Bin-Cheng Yao as co-inventors.

21. The '441 Patent has been in full force and effect since its issuance. PGI owns by assignment the entire right, title, and interest in and to the '441 Patent, including the right to seek damages for past, current, and future infringement thereof.

22. The '441 Patent "relates to a bioassay system including a plurality of optical detection apparatuses, and uses of the bioassay system for detecting and analyzing biomolecules, such as nucleic acids." Ex. 1 at 1:15-18.

23. PGI is informed and believes, and thereon alleges, that PacBio has infringed and, unless enjoined, will continue to infringe one or more claims of the '441 Patent in violation of 35 U.S.C. § 271, by, among other things, making, using, offering to sell, and/or selling within the United States, supplying or causing to be supplied in or from the United States, and/or importing into the United States, without authority or license, PacBio products, including Sequel and Sequel II ("accused products").

24. Representative claim 48 of the '441 Patent, reproduced below with the addition of the labels [a], [b], [c], and [d] corresponding to parts of the claim, recites an apparatus for identifying a single biomolecule:

48. An apparatus for identifying a single biomolecule, comprising:
 [a] a substrate having a light detector;
 [b] a linker site formed over the light detector, the linker site being treated to affix the biomolecule to the linker site; and
 [c] an excitation light source formed over the substrate;

[d] wherein the linker site is proximate to the light detector and is spaced apart from the light detector by a distance of less than or equal to 100 micrometers.

25. The accused products embody every limitation of at least claim 48 of the '441 Patent, literally or under the doctrine of equivalents, as set forth below. The further descriptions below based on Sequel are preliminary examples and are non-limiting.

"48. An apparatus for identifying a single biomolecule, comprising:"

- 26. Sequel is an apparatus.
- 27. Sequel can be used to identify the nucleic acid sequence of a DNA molecule.
- 28. A PacBio brochure explains that Sequel is “powered by single molecule, real-time (SMRT) technology.” Ex. 5 at 2 (emphasis removed).
- 29. Below is a computer-rendered image of Sequel as seen in a PacBio video, available at https://www.youtube.com/watch?time_continue=2&v=icrZbtgYpS8&t=2m10s, including a partial view of some of its internal components.



30. Among its internal components, Sequel uses SMRT Cells, which it requires for sequencing. Ex. 6; *see also* Ex. 7 at 16 (noting that SMRT Cells are “needed before sequencing on the Sequel System”). The “Supported SMRT Cell” for Sequel is the “SMRT Cell 1M”:

	Sequel II System	Sequel System
Supported SMRT Cell	SMRT Cell 8M	SMRT Cell 1M
Number of HiFi Reads >99%* Accuracy	Up to 4,000,000	Up to 500,000
Sequencing Run Time per SMRT Cell	Up to 30 hrs	Up to 20 hrs
Recommended Chemistry	1.0	3.0
Sequel Instrument Control Software	v7.0	v6.0
Performance Data	Sequel II System Release	Sequel System 6.0 Release

Ex. 2.

31. PacBio sells its SMRT Cells in various arrangements. As one example, PacBio sells a “SMRT Cell 1M v3 Tray” which it describes as a “set of four SMRT Cells compatible with Sequel Sequencing Chemistry 3.0 that can each collect up to 10 hours of sequencing data.”

Ex. 8. PacBio provides the following details for this product:

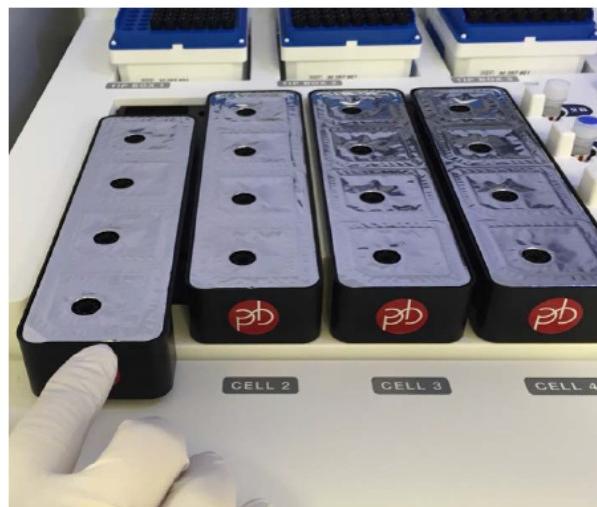
The Sequel SMRT Cell 1M v3 is a set of 4 nanofabricated consumables each patterned with approximately 1,000,000 wells called zero-mode waveguides (ZMWs). The SMRT Cell 1M v3 can acquire sequencing data up to 10 hours of collection time. . . One SMRT Cell is utilized in each sequencing collection, and SMRT Cells can be run at a time giving you flexibility in how to set up your experiments.

Ex. 8.

32. The following is an image and description of loading SMRT Cells into Sequel.

Load the SMRT® Cells and Tips onto the Instrument

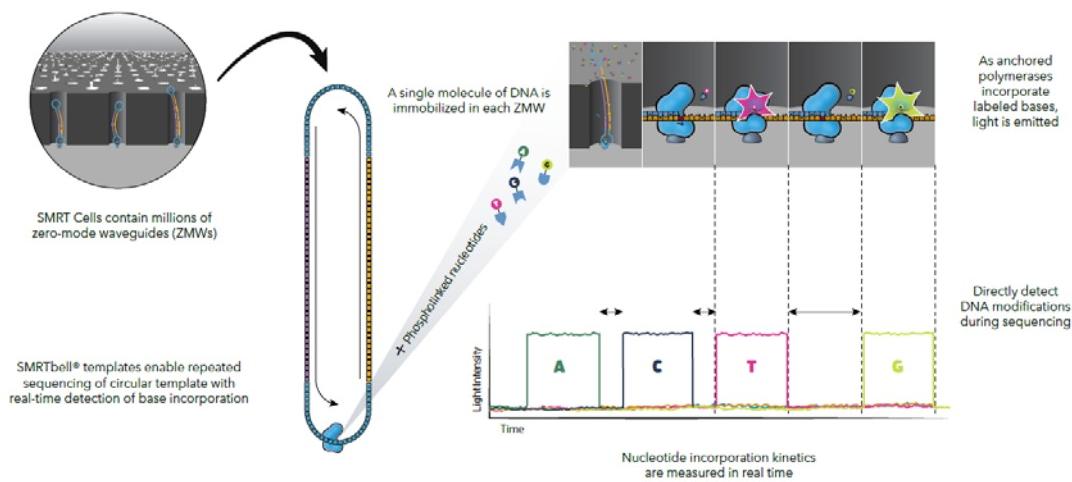
1. Place the appropriate number of SMRT Cells into the appropriate SMRT Cell slots as shown below. The SMRT Cell tray gently slides in and clicks into place. **Note:** The SMRT Cell trays are NFC-tagged for inventory tracking.



Ex. 9 at 6.

33. Each SMRT Cell contains multiple “zero-mode waveguides (ZMWs).” Ex. 10 at 2. “A single molecule of DNA is immobilized in each ZMW.” Ex. 10 at 2. PacBio has depicted this process, for example, as follows:

How SMRT Sequencing Works



Ex. 10 at 2.

34. Sequel is an apparatus for identifying a single biomolecule.

“[a] a substrate having a light detector”

35. A Sequel must be loaded with one or more SMRT Cell 1M units in order for Sequel to sequence DNA.

36. A SMRT Cell 1M from PacBio contains a microchip.

37. The microchip in a SMRT Cell 1M from PacBio has a substrate.

38. The substrate in a SMRT Cell 1M from PacBio comprises a semiconductor.

39. The semiconductor substrate in a SMRT Cell 1M from PacBio has one or more CMOS optical sensors.

40. A Sequel loaded with a SMRT Cell 1M includes a substrate having a light detector.

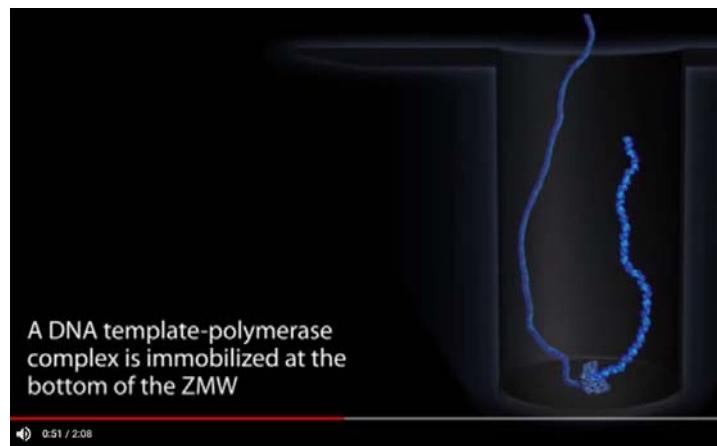
“[b] a linker site formed over the light detector, the linker site being treated to affix the biomolecule to the linker site; and”

41. A SMRT Cell 1M from PacBio includes at least one area for affixing a biomolecule over a light detector in a substrate.

42. At least one area for affixing a biomolecule over a light detector in a SMRT Cell 1M is treated to immobilize the biomolecule.

43. As depicted above, a single molecule of DNA is immobilized in each ZMW by an “anchored” polymerase. Ex. 10 at 2. PacBio’s video overview of its SMRT technology, available at https://www.youtube.com/watch?time_continue=54&v=WMZmG00uhwU&t=0m51s, explains that a “DNA template-polymerase complex is immobilized at the bottom of the ZMW,”

as depicted in the following image captured from that video. In this way the biomolecule is affixed to the linker site.



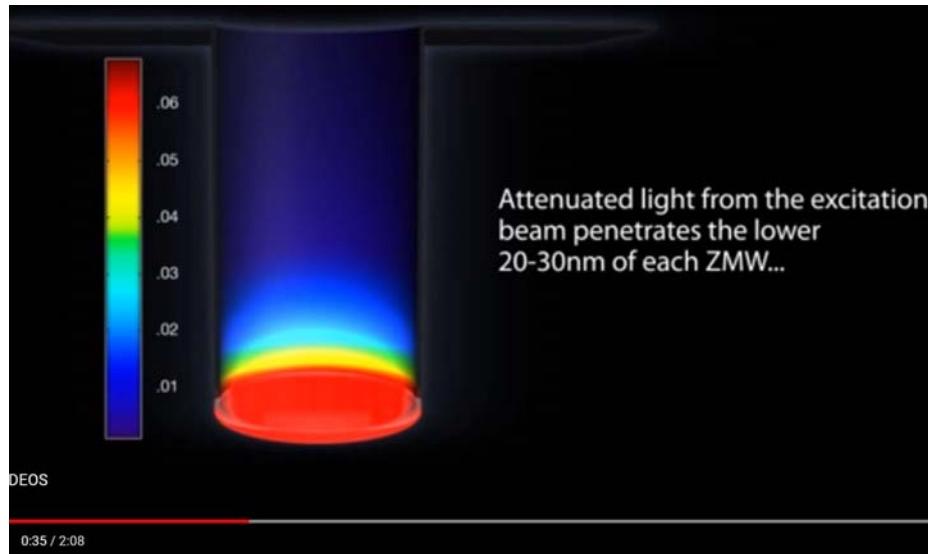
44. A Sequel loaded with a SMRT Cell 1M contains a linker site formed over a light detector in a substrate, where the linker site is treated to affix the biomolecule to the linker site.

“[c] an excitation light source formed over the substrate”

45. A SMRT Cell 1M from PacBio includes at least one excitation light source that is formed over the substrate.

46. A microchip in a SMRT Cell 1M from PacBio has a light-emitting waveguide formed over the semiconductor substrate that emits excitation light via evanescent waves to the linker site along a horizontal direction parallel to a surface of the light detector.

47. PacBio’s SMRT technology uses an excitation light source, as depicted in the following image from its video overview of SMRT technology, available at https://www.youtube.com/watch?time_continue=54&v=WMZmG00uhwU&t=0m35s:



48. PacBio further explains that as “each ZMW is illuminated from below, the wavelength of the light is too large to allow it to efficiently pass through the waveguide,” as depicted in the following image from its video overview of SMRT technology, available at https://www.youtube.com/watch?time_continue=54&v=WMZmG00uhwU&t=0m29s:



49. A Sequel loaded with a SMRT Cell 1M contains an excitation light source formed over the substrate.

“[d] wherein the linker site is proximate to the light detector and is spaced apart from the light detector by a distance of less than or equal to 100 micrometers”

50. An area for affixing a biomolecule over a light detector in a substrate of a SMRT Cell 1M from PacBio is formed over, and proximate to, the light detector.

51. An area for affixing a biomolecule over a light detector in a substrate of a SMRT Cell 1M from PacBio is spaced less than or equal to 100 micrometers above a light detector in a substrate.

52. Sequel’s SMRT Cell 1M microchip contains a linker site and a light detector separated by a distance of less than 20 micrometers.

53. A Sequel loaded with a SMRT Cell 1M contains a linker site that is proximate to the light detector and is spaced apart from the light detector by a distance of less than or equal to 100 micrometers.

54. On information and belief, PacBio uses its products, including for purposes of testing and research, and thereby also directly infringes at least representative method claim 16 of the ’441 Patent. For example, PacBio periodically releases improvements to Sequel, the development of which involves internal tests that use Sequel. *See Ex. 11 (“This release is part of our continued commitment to increasing the performance of the Sequel System, and we are very pleased with the data we are seeing both internally and at our beta-test sites . . . We are focused on improving the key applications for our customers where SMRT Sequencing provides unique advantages.”).* As another example, researchers “teamed up with scientists [at] PacBio to explore how long-read sequencing might supplement their short-read-based pipeline for gene discovery,” and the sample was “sequenced on two SMRT Cells with 20-hour movies on the Sequel System.” Ex. 12.

55. PacBio has long had knowledge of the '441 Patent. For example, as set forth in Paragraphs 11 through 14, in 2010 PacBio was aware of the provisional application to which the '441 Patent claims priority, and in the ensuing years PacBio sought to license the '441 Patent from PGI. As another example, the '441 Patent has been cited by PacBio during prosecution of its own patent applications, including during the prosecution of the applications that issued as U.S. Patent Nos. 8,465,699; 8,467,061; 8,994,946; 9,223,084; 9,372,308; 9,410,891; 9,606,068; and 9,624,540.

56. PGI is informed and believes, and thereon alleges, that PacBio actively, knowingly, and intentionally has induced infringement of the '441 Patent by, for example, controlling the design and manufacture of, offering for sale, selling, supplying, and otherwise providing instruction and guidance regarding the above-described products with the knowledge and specific intent to encourage and facilitate infringing uses of such products by its customers both inside and outside the United States. For example, PacBio publicly provides documentation, including web pages, brochures, user guides and manuals, and videos, available through PacBio's publicly accessible website, instructing customers on uses of PacBio's products that infringe the claims of the '441 Patent. *See, e.g.,* <https://www.pacb.com/products-and-services/sequel-system> (providing details on Sequel); <https://www.pacb.com/products-and-services/consumables> ("PacBio provides complete workflows and all the consumable components you need to perform [SMRT] Sequencing."); <https://www.pacb.com/products-and-services/sequel-system/software> (noting that its "SMRT Link" software is a "web-based application, designed for low- or high-throughput labs, that guides you through all steps of your Sequel System run" and providing a link to "Learn More +"); <https://www.pacb.com/applications> (webpage titled "APPLICATIONS" stating its SMRT

technology “supports numerous sequencing applications, bringing new levels of depth and quality to genetic data” and “you can elevate your research and gain a competitive edge with SMRT Sequencing,” and providing links to “DISCOVER MORE”); <https://www.pacb.com/research-focus> (webpage titled “RESEARCH FOCUS” stating “[w]e support innovative scientists in a wide variety of life science research fields” and providing links to “DISCOVER MORE” for different research uses); <https://www.pacb.com/support> (webpage titled “SUPPORT,” providing links to technical support, training materials (“including webinars, e-Modules, user guides, and more”), documentation (“[o]ur extensive database of documentation provides a complete overview of SMRT technology and its use in research settings”), and software downloads (“[o]ur collection of open-source software is designed to elevate your research efforts and enhance your sequencing capabilities”)). On information and belief, PacBio’s customers directly infringe the ’441 Patent by using, without authority or license, the accused products. For example, PacBio provides blog entries on its publicly accessible website detailing others’ use of Sequel. *See, e.g.*, <https://www.pacb.com/blog/cannabis-genome> (“More than 180 billion bases were sequenced on the Sequel system, allowing the Medicinal Genomics team to select the longest reads as the foundation for the DNA assembly process.”); <https://www.pacb.com/blog/scientists-uncover-epilepsy-causing-structural-variant-with-smrt-sequencing> (referencing a new study and noting the scientists “used the Sequel System to generate low-coverage whole genome sequencing of an affected sibling and three unrelated controls”); <https://www.pacb.com/blog/north-american-user-group-meeting-highlights-in-human-animal-insect-and-microbes> (“These complex samples can be interpreted by sequencing biological barcodes, work for which he and his team implemented the Sequel System two years

ago to replace Sanger sequencing. . . . That's why he plans to use this platform for the next phase of this study, which will involve looking at 1.5 million species.”).

57. PGI is informed and believes, and thereon alleges, that PacBio has contributed to the infringement by its customers of the '441 Patent by, without authority, importing, selling and offering to sell within the United States materials and apparatuses for practicing the claimed invention of the '441 Patent both inside and outside the United States. The above-described products constitute a material part of the invention of the '441 Patent and are not staple articles or commodities of commerce suitable for substantial noninfringing use. For example, PacBio contributes to the direct infringement of the '441 Patent by providing its customers with Sequel and Sequel II, including necessary products, such as software and “all the consumable components you need to perform [SMRT] Sequencing,” including template preparation multiplexing kits, binding and cleanup kits, “SMRT Cells and SMRT Sequencing reagents required for on-instrument sequencing,” and “multi-well plates, septa, and tips specifically designed and optimized for use with PacBio Systems.” *See Ex. 6; see also ¶ 56.* Sequel, Sequel II, and these other products, which are specifically designed to work with Sequel and Sequel II, have no other purpose than to operate in a manner that directly infringes the '441 Patent, and therefore are not staple articles of commerce and have no substantial noninfringing uses. On information and belief, PacBio knows that the above-described products constitute a material part of the invention of the '441 Patent and are not staple articles or commodities of commerce suitable for substantial noninfringing use. On information and belief, as described for example in the preceding Paragraph, PacBio’s customers directly infringe the '441 Patent by using, without authority or license, the accused products.

58. As a result of PacBio's infringement of the '441 Patent, PGI has been damaged. PGI is entitled to recover for damages sustained as a result of PacBio's wrongful acts in an amount subject to proof at trial.

59. PGI is informed and believes, and thereon alleges, that the infringement of the '441 Patent by PacBio has been and continues to be willful. As noted above, at least in Paragraphs 11-14 and 55, PacBio has long had knowledge of the '441 Patent and its need for a license to the same. PacBio has deliberately continued to infringe in a wanton, malicious, and egregious manner, with reckless disregard for PGI's patent rights. Thus, PacBio's infringing actions have been and continue to be consciously wrongful.

60. Based on the information alleged in this claim, PGI is informed and believes, and thereon alleges, that this is an exceptional case, which warrants an award of attorneys' fees to PGI pursuant to 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, PGI prays for judgment against PacBio as follows:

- A. That PacBio has infringed, and unless enjoined, will continue to infringe, the '441 Patent;
- B. That PacBio has willfully infringed the '441 Patent;
- C. That PacBio pay PGI damages adequate to compensate PGI for PacBio's infringement of the '441 Patent, together with interest and costs under 35 U.S.C. § 284;
- D. That PacBio be ordered to pay prejudgment and postjudgment interest on the damages assessed;
- E. That PacBio pay PGI enhanced damages pursuant to 35 U.S.C. § 284;

- F. That PacBio be ordered to pay supplemental damages to PGI, including interest, with an accounting, as appropriate;
- G. That PacBio be enjoined from infringing the '441 Patent, or if its infringement is not enjoined, that PacBio be ordered to pay ongoing royalties to PGI for any post-judgment infringement of the '441 Patent;
- H. That this is an exceptional case under 35 U.S.C. § 285, and that PacBio pay PGI's attorneys' fees and costs in this action; and
- I. That PGI be awarded such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), PGI hereby demands a trial by jury on all issues triable to a jury.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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